

**Notice of Allowability**

Application No.

09/875,228

Examiner

Richard Schnizer, Ph. D

Applicant(s)

YU ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/14/04.
2. ☒ The allowed claim(s) is/are 6,8-12,31,32 and 84-89.
3. ☒ The drawings filed on 22 October 2001 and amended on 11/7/02 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                    |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|   | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steve Kelber on 11/19/04.

The application has been amended as follows:

#### **IN THE SPECIFICATION:**

In the first sentence of the specification, insert --(abandoned)-- immediately after "09/127,834."

#### **IN THE CLAIMS:**

6. (currently amended) An isolated polynucleotide comprising [[a sequence having at least about 90% sequence identity to]] nucleotides about 8021 to about 8371 of SEQ ID NO:1, or a fragment thereof of comprising bases 8192-8206 of SEQ ID NO:1, wherein said polynucleotide or said fragment thereof has prostate-specific enhancer activity.

### ***Reasons for Allowance***

The specification discloses that SEQ ID NO:1 comprises a prostate specific enhancer. Deletion analysis of SEQ ID NO:1 defines a core enhancer of 1172 bases from position 7200-8371 that has full enhancer activity (about 90-fold induction in

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LNCaP cells when linked to a minimal promoter). A minimal fragment from position 8021-8371 has reduced activity, (37-fold induction). A fragment from position 8128-8263 did not show any enhancer activity. See pages 101 and 102, and Figs. 24A and 24B. The specification discloses an androgen response element at position 8192-8206 of SEQ ID NO:1. Mutations of this ARE eliminate enhancer activity of the maximally active core enhancer fragment of SEQ ID NO:1, i.e. bases 7200-8371. This ARE is located within the inactive 8128-8263 fragment of SEQ ID NO:1, so it is necessary but not sufficient for activity. See page 103, line 4 to page 104, line 6, and Fig. 11. So, it is clear that an ARE at bases 8192-8206, and at least one sequence element in bases 8021-8127 and/or 8264-8371, are required for prostate specific activity. Determining by deletion analysis the minimal fragment that retains prostate specific enhancer activity was routine in the art at the time the invention was made, so the claims are allowed.

#### ***Comment Regarding Terminal Disclaimer***

The terminal disclaimer against US Patent 6,197,294 filed 10/14/04 will not be applied because this patent is not assigned to applicant. No rejection was made over this patent.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the

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hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, John Leguyader, be reached at 571-272-0760. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.



DAVE T. NGUYEN  
PRIMARY EXAMINER